



Comparative effectiveness of Ayurveda and conventional care in knee osteoarthritis

– a randomized controlled trial (CARAKA)

Christian S. Kessler, Kartar Dhiman,
Abhimanyu Kumar, Thomas Ostermann,
Shivenarain Gupta, Antonio Morandi,
Martin Mittwede, Elmar Stapelfeldt,
Michaela Spoo, Katja Icke,
Andreas Michalsen, Claudia Witt



CHARITÉ
KRANKENHAUS

Methods

- Prospective multicentered randomized controlled trial (NCT01225133)

- Ayurvedic treatment and conventional guideline care with 15 treatments over 12 weeks each
- 2 hospital outpatient clinics and 2 private outpatient clinics with a total of 5 physicians and 20 therapists

Witt et al. *Trials* 2013, **14**:149
<http://www.trialsjournal.com/content/14/1/149>



STUDY PROTOCOL

Open Access

Comparative effectiveness of a complex Ayurvedic treatment and conventional standard care in osteoarthritis of the knee – study protocol for a randomized controlled trial

Claudia M Witt^{1,2*}, Andreas Michalsen^{1,3}, Stephanie Roll¹, Antonio Morandi⁴, Shivnarain Gupta⁵, Mark Rosenberg⁶, Ludwig Kronpaß^{6,7}, Elmar Stapelfeldt³, Syed Hissar⁸, Matthias Müller⁹ and Christian Kessler³

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Eligibility criteria

Main inclusion criteria

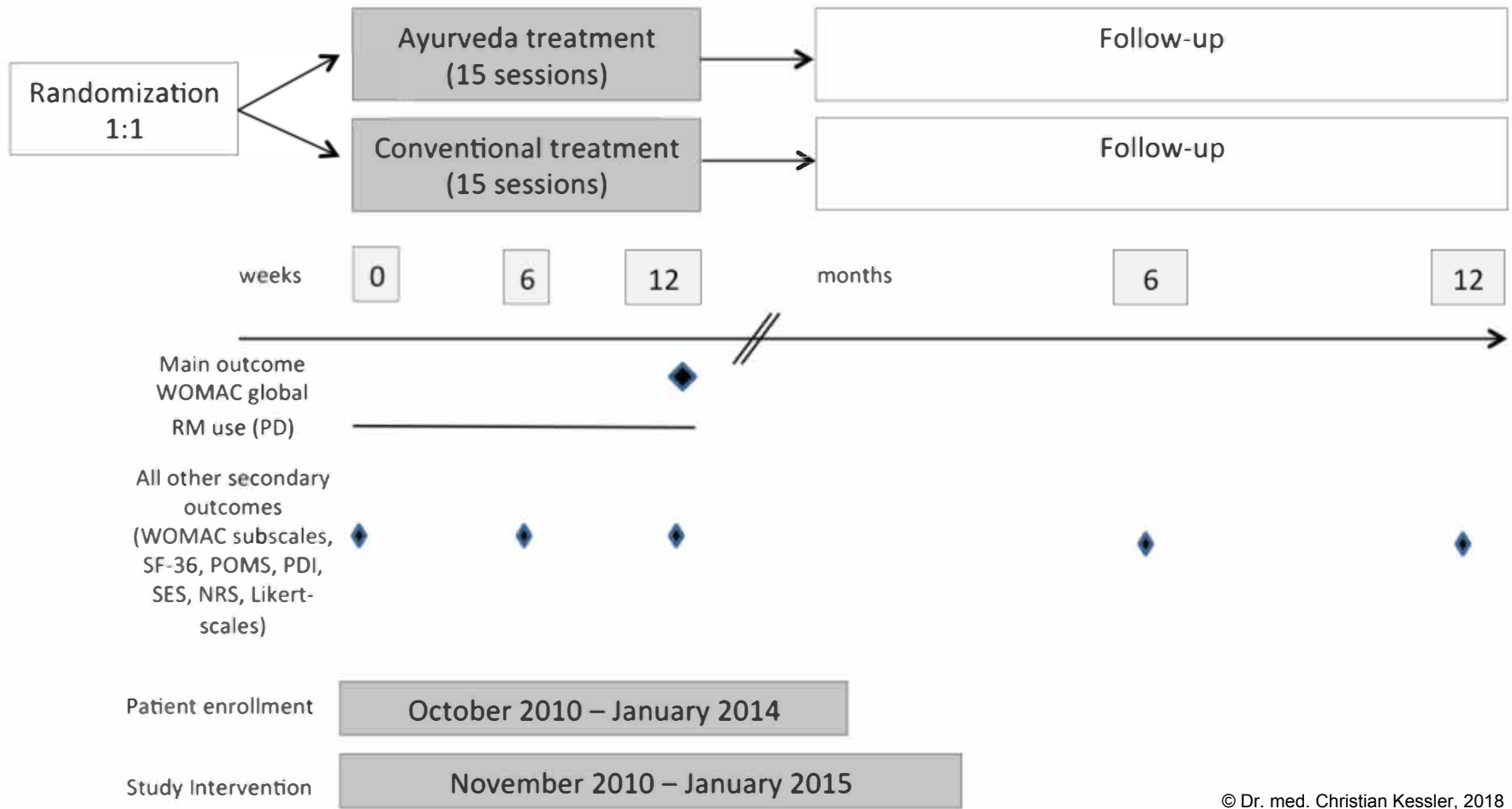
- 40 to 70 years of age, male and female
- Prediagnosed OA of the knee according to ACR criteria
- Radiologic changes in X-ray or MRI
- baseline pain intensity in the affected knee of ≥ 40 mm on a 100 mm visual analogue scale (VAS) over 7 days

Main exclusion criteria

- Pain caused by congenital dysplasia, rheumatoid arthritis, autoimmune diseases, malignancies, knee surgery or arthroscopy
- chondroprotective drugs, intra-articular injection into the affected knee-joint or beginning of a systemic medication with corticosteroids within the preceding 3 months

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Study Design



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WOMAC = Western Ontario and McMaster University Osteoarthritis Index; RM: Rescue Medication; PD: Patient Diary; SF-36 = Short Form-36 Health Survey; NRS= Numeric Rating Scales; POMS = Profile of mood states; PDI = Pain Disability Index; SES= Pain Experience Scale

Statistics

- Primary outcome: WOMAC Index change after 12 weeks
- Generalized Linear Mixed Models (GLM) adjusted for baseline values
- Missing data were multiply imputed by maximum-likelihood based regression methods

Baseline

Characteristics	Ayurveda n=77	Conventional n=74
Mean age, years (sd)	60.9 (6.5)	61.5 (6.6)
> 10 years school, n (%)	42 (56.0)	39 (52.7)
Mean duration of knee pain years (sd)	9.7 (9.1)	9.0 (7.0)
Medication intake for knee OA	34 (44.2)	39 (52.7)
WOMAC Index, mean (sd)	91.1 (40.3)	94.2 (44.4)

Primary Outcome

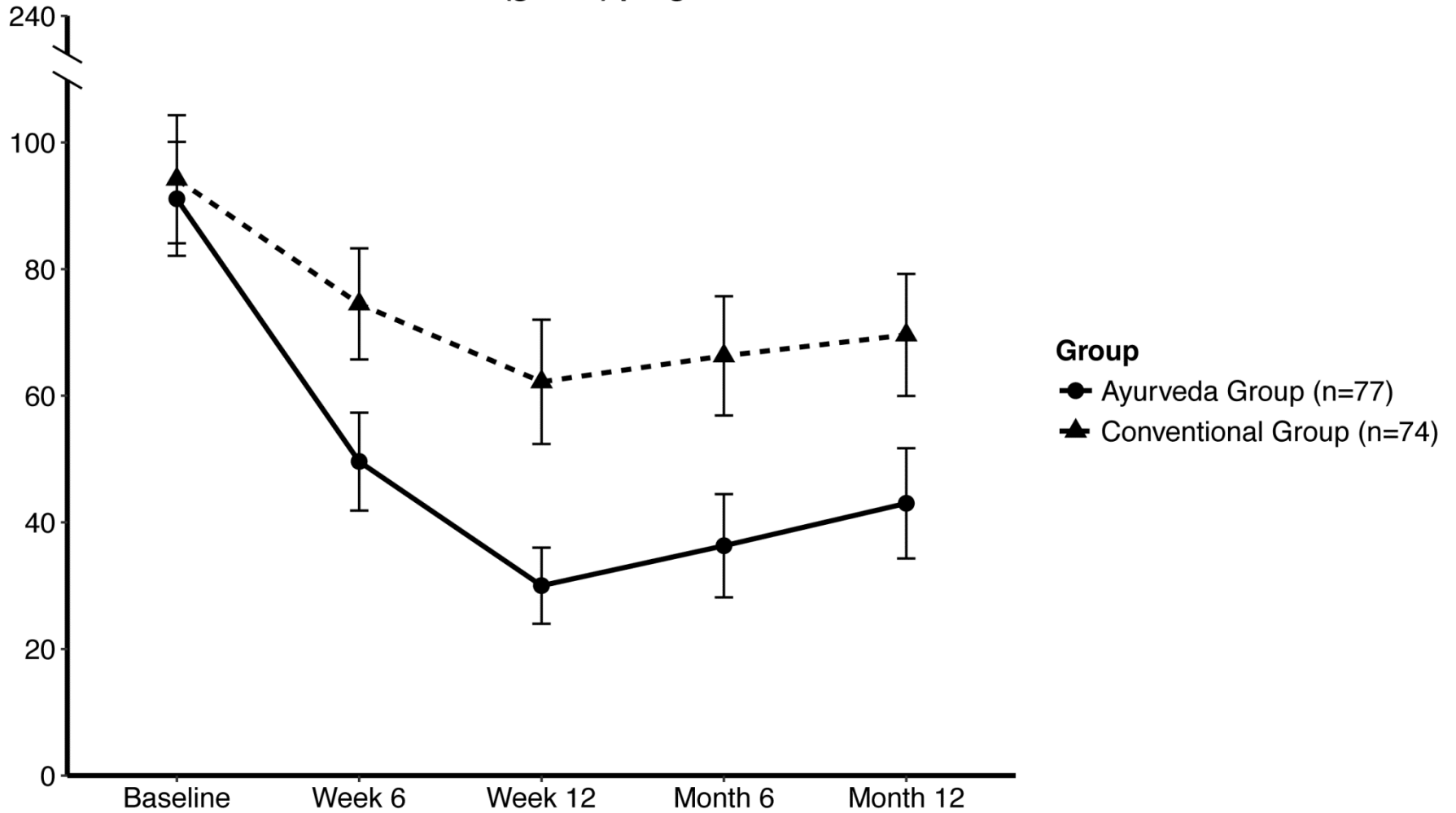
- WOMAC Index changes from baseline to 12 weeks

Changes of WOMAC Index (Baseline-week 12)	Ayurveda group	Conventional group
Mean [95% CI]	61.0 [52.4;69.6]	32.0 [21.4;42.6]

- Effect Size Cohen's d: 0.68 [95% CI:0.35;1.01]

Results

WOMAC index (global) progression



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Secondary Outcomes

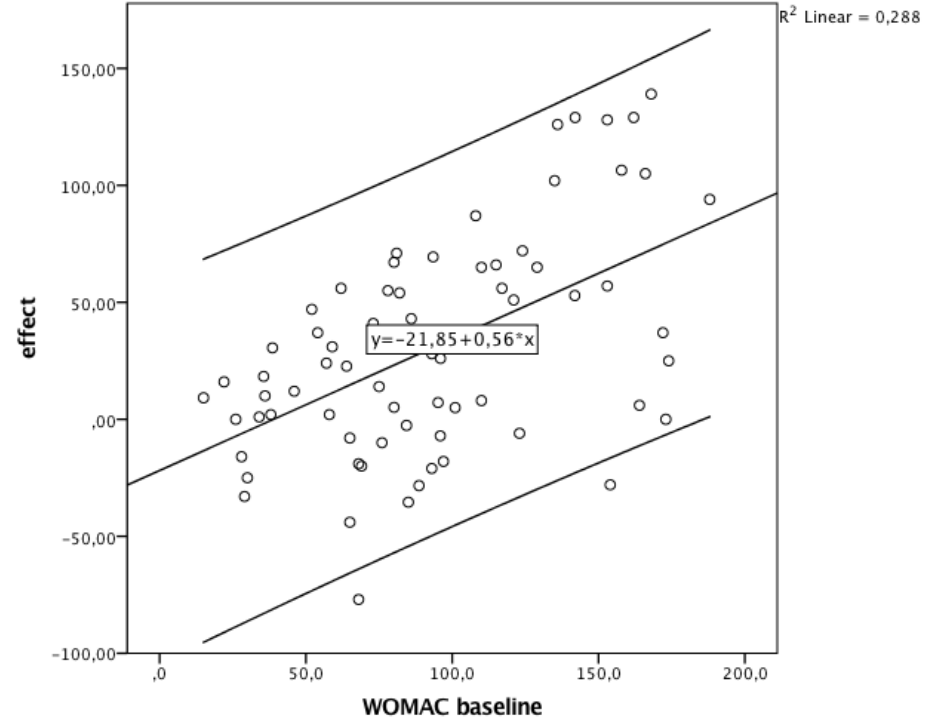
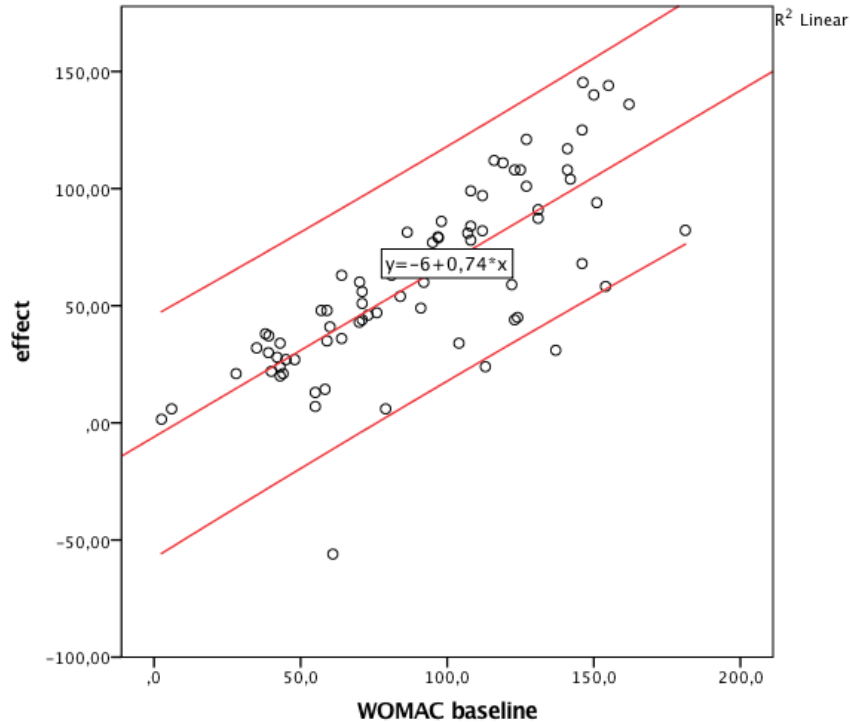
Between groups differences: Baseline – Week 12

Outcome measures	Effect size or mean [95% CI]	P-value
WOMAC		
- Pain	0.64 [0.32;0.97]	<0.001
- Stiffness	0.63 [0.30;0.95]	<0.001
- Function	0.64 [0.32;0.97]	<0.001
PDI	5.8 [2.1;9.5]	0.002
SF-36		
- Physical comp.	-6.6 [-9.3;-3.9]	<0.001
- Mental comp.	-1.7 [-5.1;1.6]	0.308

- Effects maintained up to 12 month

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Subgroup analyses: relation between WOMAC baseline value and effect size



Ayurveda: non-parametric correlation
Kendall's tau b = 0.63; $p < 0.001$
(= moderate to strong correlation)

Conventional: non-parametric correlation
Kendall's tau b = 0.34; $p < 0.001$
(= weak correlation)

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In contrast to conventional patients, almost all Ayurveda patients benefit in a similar way. The effect significantly correlates with the baseline situation

Discussion and Conclusions

Limitations

- Blinding of patients and physicians not possible
- No intraarticular corticosteroid treatment included

Strengths

- First head to head comparison study of complex multimodality Ayurveda treatment

Conclusions

- The results suggest that a complex multimodal Ayurvedic treatment might be clinically superior to a complex multimodal conventional treatment OA of the knee.